

### **REMARKS**

The Office Action dated May 11, 2004 has been received and carefully studied.

This case differs from the parent case in the addition of mildness and tissue toxicity disclosures.

All references and search reports were provided by way of an Information Disclosure Statement filed on September 28, 2001. An additional copy of the International Search Report is submitted herewith for the convenience of the Examiner.

The Examiner rejects claims 1-6, 12, 16, 18, 22 and 23 under 35 U.S.C. §103(a) as being unpatentable over the combination of each of White, Lee, Goldemberg and Vermeer in view of each of Meier and Caudry. White, Lee, Goldenberg and Vermeer are cited for their teachings of the combination of lauroyl sarcosinate and CPC as conventional components of oral care products including dentifrice and mouthwash. Meier and Caudry are cited for their disclosure of disinfectant compositions containing CPC. The Examiner concludes that it would have been obvious to disinfect dental appliances and toothbrushes with a known disinfecting solution as taught by the secondary references in combination with the method of the primary references.

The rejection is respectfully traversed with respect to White and Lee. Applicant respectfully submits that neither White nor Lee is a proper reference against this case, as this case is the National Phase of PCT /US00/01952 filed on January 26, 2000. White is effective as a reference as of its filing date of June 24, 2002, and Lee is effective as a reference as of its filing date of March 27, 2001, both of which are after the effective date of the instant PCT application.

By the accompanying amendment, the independent claims have been amended to recite respective amounts of the important components.

In a healthy mouth with normal saliva, the chemicals in conventional toothpastes that break up plaque, kill bacteria and help prevent cavities do not cause significant damage to the tissues that line the inside of the mouth. Indeed, nearly all dentrifices contain some anti-bacterial agents such as cetylpyridinium chloride, triclosan, chlorhexidine and the phenolic groups. Their function is to disrupt the membrane of bacteria and cause its death. Ionic detergents have a strong affinity for protein molecules and function to solubilize these structures. However, under conditions in which the normal environment in the mouth is altered, these chemicals can have damaging effects. Patients with diabetes, AIDS, whose who use tobacco, and senior citizens all experience a similar decrease in the protection of the mouth tissues caused by diminished saliva flow. These patients are therefore more susceptible to the potentially harmful chemicals found in most toothpastes.

The cells lining the entire mouth are replaced every 4-6 days. The outermost layer of cells protects the mouth from chemical and physical attack. If this layer is lost before the underlying replacement of cells is fully developed, extreme sensitivity and inflammation follows. Inflammation is characterized by bleeding gums and bad breath.. The body's defense mechanism responds to this attack by replacing the cells lining the mouth at a much faster rate: every 3-5 hours. Under these conditions, a greater number of immature cells becomes exposed to potentially harmful elements present in many toothpastes causing further escalation of cell damage. Bacteria thrive in this environment, which compounds the problem. Moreover, when such inflamed tissue is exposed to

preparations containing alcohol, detergents and nearly all anti-microbial agents, burning sensations and severe pain result.

The present inventor has found that toothpaste, mouthwash and disinfecting solutions that include combinations of CPC and sarcosine were irritating to tissue; no combination could effectively reduce the toxic nature of the surfactants, as cell lysing with each substance alone or together resulted in cell lysis above 60%, sometimes even as high as 90%. However, with the addition of dehydroacetic acid, cell lysis was lowered to 26%, and with the further adjustment of pH to 6.2, (such as by the addition of citric acid), to 1.4%. This is surprising and unexpected, and is nowhere disclosed or suggested by the cited art.

Goldemberg et al. do not disclose toothpastes or mouthwashes having dehydroacetic acid. Vermeer discloses dehydroacetic acid as one of many suitable antimicrobial agents, but do not disclose or suggest that the instantly claimed combination in the amounts specified has any beneficial effect, or that it reduces cell lysis. Neither secondary reference supplies this deficiency.

The Examiner rejects claims 1-6, 12-16, 18 and 22-23 under 35 U.S.C. 112, second paragraph, as being indefinite. By the accompanying amendment, the indefiniteness has been eliminated.

The remaining prior art is believed to have been properly not relied upon in rejecting any claim.

Reconsideration and allowance are respectfully requested in view of the foregoing.

Respectfully submitted,



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